

Using the 4 Pillars to Increase Vaccination Among High-Risk Adults: Who Benefits?

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Adults with certain chronic medical conditions are at higher risk of complications from some vaccine-preventable diseases because these conditions are known to compromise the immune response to infection or increase vulnerability to the effects of infection.¹⁻³ For example, among adults aged 18 to 64 years, rates of pneumococcal pneumonia are 3.0 to 9.8 times higher for those with chronic heart disease, lung disease, or diabetes compared with healthy adults; for invasive pneumococcal disease, rates are 3.6 to 7.7 times higher.³ Not only are vaccination rates for this group woefully low—20.3% for pneumococcal polysaccharide vaccine (PPSV) in 2014⁴—and far from the Healthy People 2020 goal of 60%,⁵ there are significant disparities in rates by race,⁶ health insurance status, and frequency of contact with a medical provider.⁷ Although the 2013 influenza vaccination rate among high-risk adults (49.5%) was higher than that among those without high-risk conditions (32.9%),⁸ this value is also below the US goal of 70%.⁵ Tetanus, diphtheria, and pertussis (Tdap) vaccine uptake among all adults 19 years or older was 20.1% in 2014.⁴

Recent research on interventions to improve vaccination among high-risk adults is scant. Two studies focused on specialized high-risk populations (patients on dialysis⁹ and American Indians with diabetes¹⁰). The interventions increased PPSV uptake to 65.5% and 92%, respectively, through extensive provider and patient education and outreach to patients, including home vaccination visits. Among patients on dialysis⁹ and veterans with spinal cord injuries,¹¹ multicomponent interventions resulted in increases in influenza vaccine uptake of 4 to 5 percentage points (PP).

We undertook a 2-year study of 18 primary care practices to test the effectiveness of an intervention designed to increase uptake of adult vaccines using the 4 Pillars Practice Transformation Program (4 Pillars Program). This program is a step-by-step guide for medical practices to implement evidence-based strategies for increasing vaccination rates in primary care or other outpatient settings.¹² These strategies are applicable to many practice settings and populations. Overall findings from the randomized controlled cluster trial (RCT) and pre-post studies have been published.¹³⁻¹⁵

ABSTRACT

OBJECTIVES: To compare changes in vaccination rates (pneumococcal polysaccharide vaccine [PPSV]; tetanus, diphtheria, and pertussis [Tdap] vaccine; and influenza vaccine) among high-risk adults following an intervention (June 1, 2013, to January 31, 2015) that used the 4 Pillars Practice Transformation Program (4 Pillars Program).

STUDY DESIGN: Post hoc analysis of data from a randomized controlled cluster trial.

METHODS: Eighteen primary care practices received staff education, guidance for using the 4 Pillars Program, and support for a practice immunization champion. Paired *t* tests were used to compare vaccination rates separately for those with diabetes, chronic lung or chronic heart disease, or other high-risk conditions. Student's *t* tests were used to compare vaccination rates across high-risk conditions. Generalized estimating equation modeling was used to determine the likelihood of vaccination.

RESULTS: Based on *International Classification of Diseases, Ninth Revision, Clinical Modification* codes, 4737 patients aged 18 to 64 years were identified as having diabetes (*n* = 1999), chronic heart disease (*n* = 658), chronic lung disease (*n* = 1682), or another high-risk condition (*n* = 764). PPSV uptake increased by 12.2 percentage points (PP), Tdap vaccination increased by 11.4 PP, and influenza vaccination increased by 4.8 PP. In regression analyses, patients with diabetes (odds ratio [OR], 2.2; 95% CI, 1.80-2.73), chronic lung disease (OR, 1.50; 95% CI, 1.21-1.87), or chronic heart disease (OR, 1.32; 95% CI, 1.02-1.71) were more likely to receive PPSV than those without the respective high-risk condition. Those with diabetes (OR, 1.14; 95% CI, 1.01-1.28) or chronic lung disease (OR, 1.14; 95% CI, 1.01-1.30) were more likely to receive an influenza vaccine than those without the respective condition. The likelihood of Tdap vaccination was not significantly associated with any of the chronic conditions tested.

CONCLUSIONS: An intervention including the 4 Pillars Program was associated with significant increases in vaccination of high-risk adults. However, the overall uptake of recommended vaccines for those with high-risk conditions remained below national goals.

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TAKEAWAY POINTS

Using the 4 Pillars Practice Transformation Program (4 Pillars Program), primary care practices can achieve meaningful improvements in adult vaccination rates among high-risk adults younger than 65 years, who are historically a group with low vaccine uptake.

- ▶ There remains a gap between current vaccine uptake and national goals for high-risk adults.
- ▶ The 4 Pillars Program provides step-by-step guidance for implementing evidence-based strategies to improve vaccine uptake.
- ▶ In the program, those with diabetes were more likely to receive the pneumococcal polysaccharide vaccine than those with other high-risk conditions.

The purpose of this study was to compare the effect of the intervention on adult PPSV, influenza, and Tdap vaccination rates and likelihood of vaccination among adults aged 18 to 64 years with the 3 most common high-risk medical conditions (diabetes, chronic lung disease, and chronic heart disease) in a post hoc analysis.

METHODS

The trial was approved by the Human Research Protection Office of the University of Pittsburgh. The methods have been published previously¹⁴ and are briefly presented herein.

Sample Size and Sites

Eligible primary care family medicine (FM) and internal medicine (IM) practices from a practice-based research network in Pittsburgh (FM PittNet), a clinical network in southwestern Pennsylvania (Community Medicine, Inc), and a safety-net clinical network in Houston were solicited for participation. When 25 sites (a sufficient number per sample size calculations for an RCCT) had agreed to participate, solicitation ceased. All sites used a common electronic health record (EHR), EpicCare. Eligibility requirements included having at least 100 patients 18 years or older, preliminary baseline vaccination rates less than 50% for at least 1 adult vaccine (influenza, pneumococcal, Tdap), and a willingness to make office changes to increase vaccination rates. Participating practices were stratified by location (urban, suburban, or rural) and discipline (FM or IM), then randomized. The practices in this analysis were the 18 private practices or residency sites in southwestern Pennsylvania and did not include 1 site in Pittsburgh, which dropped out, and 6 publicly funded practices in Houston, from which data on high-risk conditions were not available.

4 Pillars Program and Intervention

The 4 Pillars Program^{14,15} is founded on 4 evidence-based^{16,17} key domains: Pillar 1: convenient vaccination services; Pillar 2: communication with patients about the importance of immunization and the availability of vaccines; Pillar 3: enhanced office systems to facilitate immunization; and Pillar 4: motivation through an office immunization champion (IC). The 4 Pillars Program includes

background on the importance of protecting patients against vaccine-preventable diseases, barriers to increasing vaccination from both provider and patient perspectives, and strategies to eliminate those barriers. Practices were expected to implement strategies from each of the 4 pillars.

The intervention was designed using the diffusion of innovations theory¹⁸ and included the 4 Pillars Program, provider education, and 1-on-1 coaching of the IC for each practice.

The IC was responsible for using the 4 Pillars Program to guide the practice's intervention activities, participating in the biweekly telephone call with a research liaison for coaching, ensuring that chosen strategies were being implemented, and working to maintain motivation of the staff.

The overall study included a 2-year RCCT in which the year 1 controls were crossed over into active intervention and the year 1 intervention groups became maintenance groups after the first year.¹²⁻¹⁴ In this analysis, all patients from the 18 southwestern Pennsylvania sites were combined and vaccination among eligible high-risk patients was examined at the end of baseline (May 31, 2013) and the end of the intervention (January 31, 2015), at which time all sites had completed the intervention. The effects of the intervention among the types of high-risk conditions were compared in a post hoc analysis.

Data Collection

De-identified demographic data (date of birth, sex, race, health insurance coverage as a proxy for income); office visit dates; *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes for high-risk conditions, including immune and autoimmune diseases, cancers, chronic kidney diseases, diabetes, chronic lung diseases, and chronic heart diseases (codes 42, 135, 141-208.91, 250.0-250.93, 279-279.9, 282.6-284, 288-288.2, 393-398.99, 402.0-404.93, 410-412, 141-141.9, 416-416.9, 428-428.9, 438-438.9, 446-446.7, 491-496, 500-505, 506.4, 506.9, 508-508.9, 510-510.9, 513-519.9, 571-572.8, 585-586, 710-710.9, and 714-714.9) (see [eAppendix Table](#) [eAppendix available at [ajmc.com](#)]); and vaccination data (vaccines given and dates) were derived from de-identified EHR data extractions. A longitudinal database was created with only those patients who were aged 18 to 64 years at baseline and who had a visit each year during the study period, creating the cohort of individuals for study.

Statistical Analyses

Descriptive analyses were performed for patient demographic characteristics (age, sex, race, health insurance, high-risk condition). Age was used as a continuous variable, and racial groupings were non-Hispanic white and nonwhite. Patients with more than

TABLE 1. Cumulative Pneumococcal Polysaccharide, Tdap, and Influenza Vaccination Rates Among High-Risk Patients Aged 18 to 64 Years*

High-risk Group	Pneumococcal Polysaccharide Vaccine			Tdap Vaccine			Influenza Vaccine		
	May 31, 2013 ^b	January 31, 2015 ^c	PPD	May 31, 2013 ^b	January 31, 2015 ^c	PPD	May 31, 2013 ^b	January 31, 2015 ^c	PPD
Diabetes n = 1999	52.5	66.2	13.7*	36.7	48.0	11.3*	53.7	58.6	5.0**
Chronic lung disease n = 1682	42.5	54.0	11.5*	39.2	49.9	10.7*	51.2	55.3	4.2**
Chronic heart disease n = 658	46.4	58.5	12.1*	34.8	46.0	11.3*	56.4	59.4	3.1
All other high-risk conditions n = 764	29.6	39.1	9.6*	38.7	51.4	12.7*	51.4	57.3	5.9**
All high-risk conditions n = 4737	43.5	55.7	12.2*	37.9	49.4	11.4*	52.1	56.8	4.8*

PPD indicates percentage point difference; Tdap, tetanus, diphtheria, and pertussis.

*Represents individual patients, not diagnoses, as there are 366 individuals with 2 or more high-risk diagnoses. Those vaccinated with pneumococcal polysaccharide or Tdap vaccine at the end of baseline were not included in the analyses.

^bPercent vaccinated by end of baseline (5/31/2013).

^cPercent vaccinated by end of intervention (1/31/2015).

** indicates $P < .001$; ***, $P < .05$.

1 of the 3 high-risk conditions (diabetes, chronic lung disease, chronic heart disease) were included in each of their respective disease groups for analysis. PPSV and Tdap would typically be administered once during the project period; thus, PPSV and Tdap rates are presented as cumulative rates at the end of baseline (May 31, 2013) and end of the intervention (January 31, 2015). For influenza vaccination, the analytical periods were June 1, 2012, to May 31, 2013, for baseline, and June 1, 2014, to January 31, 2015, for the intervention year. Proportions were reported for categorical variables, and means and standard deviations were reported for continuous variables. The primary outcome measures were the cumulative PPSV and Tdap vaccination rates, influenza vaccination rates reported at the end of baseline and the end of the intervention, and PP differences. Student's paired *t* tests were performed to test for 2-year differences in influenza vaccination rates and cumulative PPSV and Tdap vaccination rates. In addition, the weighted average vaccination rates were compared between high-risk conditions for each vaccine using Student's *t* test.

Multilevel generalized estimating equation modeling, which accounts for the clustered nature of the data (ie, patients are clustered within practices), was conducted using vaccination status for each vaccine as the binary outcome variable. Those who received the PPSV or Tdap vaccine prior to the trial were excluded from the regression analyses. To determine which factors were related to PPSV, Tdap, and influenza vaccine uptake, the regression models also accounted for heterogeneity in demographic characteristics, including age, sex, race, and health insurance. Statistical significance of 2-sided tests was set at a type I error (alpha) equal to 0.05. All analytical procedures were performed using SAS version 9.4 (SAS Institute; Cary, North Carolina).

RESULTS

Among the 4737 patients aged 18 to 64 years who had a high-risk condition, the average age was 52.1 ± 10.2 years, with 54.2% female patients, 8.2% nonwhite patients, and 65.4% who were privately insured (data not shown). In this cohort, 42.2% of patients had diabetes, 35.5% had chronic lung disease, 13.9% had chronic heart disease, and 16.1% had another high-risk condition. Overall, 366 (7.7%) had 2 or more high-risk conditions.

Cumulative PPSV uptake at the end of intervention reached 55.7% for all high-risk patients. Specifically, 59% of those with chronic heart disease, 54% with chronic lung disease, 66% with diabetes, and 39% with another high-risk condition had received PPSV by the end of the intervention (Table 1). Overall cumulative pneumococcal vaccination rates significantly increased 12.2 PP from baseline; patients with diabetes had larger increases than those with chronic lung disease ($P = .02$), chronic heart disease ($P = .032$), or another high-risk condition ($P = .009$). Cumulative Tdap vaccination rates increased significantly for all high-risk patients by 11.4 PP from baseline, reaching nearly 50% at the end of the intervention. Vaccination rates for the various high-risk groups ranged from 46% to 51%. Only those with other high-risk conditions increased their rates significantly more than those with diabetes (12.7 PP vs 11.3 PP, respectively; $P = .04$). Annual influenza vaccination also increased significantly from baseline for those with diabetes, chronic lung disease, and other high-risk conditions, reaching 57% for all high-risk patients. There were no differences among high-risk groups for PP increases in influenza vaccination rates.

In regression analyses (Table 2), 2060 patients who had received PPSV before the study began (June 1, 2012) were excluded from the PPSV regression model; similarly, 1796 patients who had received

TABLE 2. Odds of Receipt of Pneumococcal Polysaccharide, Tdap, and Influenza Vaccines Among High-Risk Patients Aged 18 to 64 Years, Adjusted for Demographics and Comorbidity Using Logistic Regression^a

Variable	Pneumococcal Polysaccharide Vaccine n = 2677		Tdap Vaccine n = 2941		Influenza Vaccine n = 4737	
	Odds Ratio (95% CI)	P	Odds Ratio (95% CI)	P	Odds Ratio (95% CI)	P
Female, ref = male	1.16 (0.98-1.37)	.086	0.83 (0.70-0.99)	.034	1.24 (1.12-1.37)	<.001
Age (years)	1.02 (1.01-1.02)	<.001	1.00 (0.99-1.00)	.333	1.03 (1.03-1.04)	<.001
White race, ref = nonwhite	1.45 (1.02-2.06)	.036	0.99 (0.72-1.36)	.953	1.20 (1.00-1.45)	.055
Medicaid, self-pay, uninsured, ref = commercial insurance	1.21 (0.97-1.50)	.084	0.82 (0.65-1.04)	.106	1.04 (0.91-1.78)	.602
Diabetes, ref = no diabetes	2.22 (1.80-2.73)	<.001	0.84 (0.68-1.03)	.093	1.14 (1.01-1.28)	.039
Chronic lung disease, ref = no chronic lung disease	1.50 (1.21-1.87)	<.001	0.84 (0.68-1.04)	.115	1.14 (1.01-1.30)	.038
Chronic heart disease, ref = no chronic heart disease	1.32 (1.02-1.71)	.036	0.83 (0.64-1.09)	.182	1.11 (0.97-1.30)	.168

ref indicates reference; Tdap, tetanus, diphtheria, and pertussis.
^aBold indicates significance at the P <.05 level.

the Tdap vaccine before the study began were excluded from the Tdap vaccine regression model. The odds of pneumococcal vaccination were significantly associated with older age (odds ratio [OR], 1.02; 95% CI, 1.01-1.02), white race (OR, 1.45; 95% CI, 1.02-2.06), and having diabetes (OR, 2.22; 95% CI, 1.80-2.73), chronic lung disease (OR, 1.50; 95% CI, 1.21-1.87), and chronic heart disease (OR, 1.32; 95% CI, 1.02-1.71). The odds of Tdap vaccination were inversely associated with being female (OR, 0.83, 95% CI, 0.70-0.99; reference = males). The odds of influenza vaccination were associated with being female (OR, 1.24; 95% CI, 1.12-1.37), with being older (OR, 1.03; 95% CI, 1.03-1.04), with having diabetes (OR, 1.14; 95% CI, 1.01-1.28), and with having chronic lung disease (OR, 1.14; 95% CI, 1.01-1.30).

DISCUSSION

With a concerted effort, primary care practices were capable of modifying their offices' systems to significantly improve vaccination rates from baseline levels among high-risk adults younger than 65 years. For pneumococcal vaccine, these results (56%) are in stark contrast to the 2014 national rate of 20%,⁴ and among those with diabetes (66%), the rate surpasses the national goal of 60%.⁵ Moreover, the improvement of 12.2 PP is notably higher than secular trends of less than 2 PP per year recently observed among adults aged 19 to 64 years with high-risk conditions.^{4,19,20} Female sex, older age, and white race were related to higher likelihood of receipt of PPSV, similar to recent national data that indicate significantly lower rates among nonwhites compared with whites⁶ and higher rates among older than younger individuals.⁴ In this study, those with diabetes, chronic lung disease, or chronic heart disease were more likely to receive PPSV than patients without each

respective high-risk condition. The risk of pneumococcal disease is increased for all 3 of these comorbidities²¹; thus, it is important to know if an intervention shown to be effective among all adults is similarly effective among high-risk adults or if a special intervention is necessary. These data indicate that high-risk adults do not require a separate intervention, as their increases in PPSV uptake approached increases reported in a study of all adults.¹⁴

Tdap vaccine uptake also increased significantly from baseline (by 11.4 PP to 49.4%). These values exceeded the 2015 national rate (20.1%), recent secular trends of 3 PP per year increased uptake for all adults older than 19 years,^{4,19,20} and the increases among all adults (6.2 PP) shown in a previous study.¹³ Interestingly, in this study, men with high-risk conditions were more likely to receive the Tdap vaccine, whereas increased rates among women might be expected given the recommendation for pregnant women²² and others who care for infants to receive the Tdap vaccine. Influenza vaccination increased significantly from baseline (3.1-5.9 PP) for those with any high-risk condition. Those with diabetes and those with chronic lung disease were more likely to have received the influenza vaccine compared with those without these conditions, whereas those with chronic heart disease were not more likely to be vaccinated against influenza than those without. Influenza vaccination rates for all groups were still considerably below Healthy People 2020 goals of 70%,⁵ a troubling finding given their high risk of influenza complications.

Barriers to adult vaccination include patient, provider, and health system issues, such as lack of awareness of the need for vaccination, competing priorities for the physician, and incomplete documentation of vaccination history.²³ The Task Force on Community Preventive Services recommends provider reminders and a combination of interventions to increase vaccination coverage among high-risk adults.²⁴ The 4 Pillars Program offers strategies

to address each of these types of barriers, including assessing and communicating the need for vaccination by all members of the clinical staff, implementing best practice alerts in the EHR or other reminders to providers, offering simultaneous vaccination with other indicated vaccines, and using standing order protocols. In an RCCT, the 4 Pillars Program demonstrated modest improvements in vaccination rates for all 3 vaccines among all adults.¹³⁻¹⁵ Other studies have used similar multifaceted approaches to increasing pneumococcal and influenza vaccination^{25,26} with moderate success.

Limitations

The pneumococcal vaccine is recommended for cigarette smokers.²¹ We did not specifically include smokers without high-risk medical conditions and therefore do not know how their inclusion would have changed the vaccination estimates. The completeness and accuracy of ICD-9-CM coding was not verified, although EHRs were used. Other records (eg, pharmaceuticals as a proxy for diagnoses) were not evaluated to confirm or augment ICD-9-CM codes. Separate analyses of uncommon ICD-9-CM codes were not done due to funding and time limitations. The population is limited to the greater Pittsburgh region and may not be generalizable to other populations. This is a post hoc analysis derived from an RCCT. The primary purpose of the analysis was to compare the effect of the intervention on groups of adults with common high-risk conditions rather than demonstrate its effectiveness against no program; hence, before-and-after analyses were conducted.

CONCLUSIONS

An intervention including the 4 Pillars Program, staff education, and support for a practice-based IC was associated with significant increases in PPSV, Tdap, and influenza vaccination among high-risk adults aged 18 to 64 years over a 2-year study. These findings further support the use of evidence-based strategies as part of a comprehensive, practice-based effort to address low vaccination rates among adults with high-risk medical conditions. Providers should be aware that the systems that are being successfully used to improve vaccination of non-high-risk patients may be equally effective for vaccinating patients with high-risk conditions. ■

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CJL); statistical analysis (SZ, CJL); provision of patients or study materials (JMR); obtaining funding (RKZ); administrative, technical, or logistic support (KKM, JMR, RKZ); and supervision (MPN, RKZ).

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eAppendix Table. High-risk Conditions, *ICD-9* Codes, and Number of Patients

High-risk Condition	<i>ICD-9</i> codes	n
Diabetes	250.0-250.93	1999
Chronic lung diseases	491.0-496; 500-505; 506.4; 506.9; 508-508.9; 510-510.9; 513-519.9	1682
Chronic heart diseases	393-398.99; 402.0-404.93; 410-412; 414.0- 414.9; 416.0-416.9; 428.0-428.9;	658
Subtotal		
≥2 (diabetes, lung disease, heart disease)		(366)
		2877
Other high-risk conditions, ie, HIV, other immune disorders, autoimmune disorders, cancers/malignancies, sickle cell disease, kidney disease	42; 135; 141-208.91; 279-279.9; 282.6-284; 288-288.2; 438-438.9; 446-446.7; 571-572.8; 585-586; 710-710.9; 714-714.9	764
Total		4737